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3D PRINTED HANDS-FREE ULTRASOUND PROBE HOLDER WITH MULTIANGLE NEEDLE GUIDE SYSTEM VERSUS CONVENTIONAL ULTRASOUND METHOD FOR POST OPERATIVE TRANSVERSUS ABDOMINIS PLANE BLOCK FOR LOWER SEGMENT CAESAREAN SECTION – A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background:

Effective post-operative pain management is essential following lower segment caesarean sections (LSCS). The Transverse Abdominal Plane (TAP) block, performed under ultrasound guidance, is a widely used technique to provide post-operative analgesia. However, conventional ultrasound methods require continuous manual probe handling, which can lead to inconsistencies in needle placement and increased operator fatigue. This study evaluates the efficacy of a 3D-printed hands-free reusable ultrasound probe holder with a multi-angle needle guide system compared to the conventional handheld ultrasound method in performing TAP blocks for LSCS patients.

Methods:

This study was conducted in two phases. Phase I involved the designing development of the product. Phase II involved the randomized controlled trial with 60 patients undergoing elective LSCS who required post-operative TAP block for pain management. Participants were divided into two groups: (1) TAP block using the 3D-printed hands-free probe holder with a multi-angle needle guide system and (2) TAP block using the conventional handheld ultrasound method. Primary outcomes included comparing the efficacy, ergonomics and ease of the anaesthesiologist to perform the block.

Results:

Preliminary findings suggest that the 3D-printed hands-free probe holder reduced procedural time compared to the conventional method. Patients in the intervention group reported comparable VAS scores and required comparable amount of rescue analgesia postoperatively implying that the device is as precise as the conventional method. Furthermore, operators found the hands-free system ergonomically advantageous, reducing strain and enhancing precision during needle guidance.

Conclusion:

The 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is more ergonomic in providing USG guided TAP block compared to the conventional method of USG guided TAP block.

INTRODUCTION

The lower segment caesarean section (LSCS) is among the most frequently performed major surgical procedures globally. Post-operative pain after LSCS can greatly affect a mother's ability to move early and care for her newborn. Effective pain management is thus a critical component of post-operative care in obstetric anaesthesia.

In the early era, pain relief post LSCS primarily relied on high doses of opioids like morphine administered via injection, often leading to significant side effects like nausea, vomiting, and respiratory depression.The introduction of spinal and epidural anesthesia for LSCS improved intraoperative pain control and laid the groundwork for post-operative pain management through continuous infusions of local anesthetics, with or without opioids.The current standard of care emphasizes a multimodal approach combining different types of pain medication, such as NSAIDs, and low-dose opioids, to optimize pain relief while minimizing side effects.

Advances in regional anesthesia like targeted nerve blocks are being explored to further improve post-operative pain management.The transversus abdominis plane (TAP) block was first described in 2001 by Dr. Rafi as a regional anesthesia technique to anesthetize the nerves of the anterior abdominal wall.

The transversus abdominis plane (TAP) block is a regional anesthesia technique that effectively relieves pain after abdominal surgeries, including LSCS. It involves injecting a local anesthetic into the fascial plane between the internal oblique and transversus abdominis muscles, targeting the thoracolumbar nerves. While the TAP block is beneficial, its efficacy can be influenced by the technique used to perform it, the tools available, and the skill of the anesthesiologist.

Recent advancements in medical technology have introduced innovative tools such as 3D printed ultrasound probe holders designed to enhance the precision and efficiency of procedures like the TAP block. This study investigates the effectiveness of a 3D printed hands-free reusable ultrasound probe holder with a multi-angle needle guidance system, comparing it with the conventional method of ultrasound-guided TAP block.

A conventional USG guided TAP block requires two people to perform. One person is required for holding the USG probe and guiding the needle and another person for the delivery of drugs. The 3D printed hands-free reusable ultrasound probe holder with multi angle needle guide system can be attached to the operating table and requires only one person to perform the procedure as it holds both the needle and the problem in a fixed position.

Our objective is to evaluate the efficacy of the 3D printed hands-free reusable ultrasound probe holder with multi angle needle guidance system by comparing it with conventional method of USG guided TAP block.

MATERIALS AND METHODS

Study design

We conducted this study as a randomised control trial in 60 parturients who met the study criteria and who underwent lower segment caesarean section under spinal anaesthesia in Saveetha Medical College Hospital.

Study duration

The duration of the study was for 6 months after CTRI approval and institutional ethics committee approval.

Sample size

With Anticipated Mean Difference of VAS score between study groups as 2.5 and Anticipated SD as 2.7, the minimum sample size per group is 30 with 90% power and 5% level of significance.

Total is 60

By using the formula:

$$n = \frac{(z\alpha + z\beta)2\ 2\ SD2}{MD2}$$

Where Z= Z statistic at a level of significance

MD= Anticipated mean difference.

SD= Anticipated Standard deviation.

METHODOLOGY

Following approval from the Institutional Ethics Committee and CTRI, written informed consent was obtained from 60 parturients aged over 18 years (ASA physical status classification 2 and 3) who were scheduled for elective lower segment caesarean section.

Inclusion criteria:

1. Pregnant women
2. Patients of ASA 2 and 3
3. Elective LSCS under spinal anaesthesia
4. Patients of age > 18 years

Exclusion criteria:

1. ASA > 3
2. Patients with body weight < 50 kgs
3. Patients with bleeding diathesis
4. Patients with infection at the site of needle insertion
5. Patients with severe eclampsia / pre-eclampsia
6. Patients who had intra operative complications like PPH

Study Procedure

Sixty patients meeting the eligibility criteria were enrolled in the study. After obtaining informed consent, they were randomly assigned to two groups using a computer-generated randomization method.

The two groups were:

1. **Group PH:** Patients who underwent USG guided TAP block using the probe holder

2. **Group C:** Patients who underwent USG guided TAP block using conventional method

As per usual hospital practice, pre anaesthetic evaluation was done. Patients were kept nil per oral for at least 6 hours prior to surgery. Upon arrival at the operating theatre, routine monitoring devices were connected to the patient, including non-invasive blood pressure, electrocardiography, pulse oximetry. 18G IV cannula was secured and Ringer Lactate infusion was started. All patients were preloaded with 500 ml of IV fluids before administration of spinal anaesthesia. All the study subjects will receive a standard spinal anaesthetic consisting of 2 ml of 0.5% hyperbaric Bupivacaine with 25 mcg of Inj. Fentanyl as an adjuvant.

At the end of the surgery, bilateral USG guided TAP block will be performed by the investigating anaesthesiologist using 30 ml of Inj. 0.25% Bupivacaine either using 3D printed hands-free reusable ultrasound probe holder with multi angle needle guide system (group PH) or conventional USG method (group C) depending on the group allocated. The procedure will be performed using aseptic technique by the same anaesthesiologist for both group patients. After disinfecting the skin with an antiseptic solution, a linear high-frequency ultrasound probe (6-13 MHz) will be positioned transversely on the anterolateral abdominal wall between the iliac crest and the costal margin.

In Group PH, the USG probe was attached to the 3D printed reusable USG probe holder with multi angle needle guide system. The probe along with the holder is then placed in the landmark of TAP block and under USG guidance, the three layers of muscles - external oblique, the internal oblique, and the transversus abdominis will be identified which can be adjusted using the 360-degree swivel mechanism provided in the probe holder. When the desired image is obtained in the monitor, the probe holder is tightened using the tightening mechanism so that it stays in place. The needle is then inserted through the needle guide system in the desired angle which is held steadily by the device. A 22-gauge, 9 cm spinal needle connected via flexible tubing to a syringe filled with the drug will be used to administer the block. After aspirating to rule out accidental vascular puncture, the drug (15 ml of Inj. 0.25% Bupivacaine) for performing the block is delivered through the needle inserted through the needle

guide system by the same person who can deliver the drug and visualize the spread of the drug from the monitor. The same procedure is done in the other side. If adequate views are not achieved, the TAP block will not be administered.

In Group C, the block was performed using conventional method without the newly developed device.

After the procedure was completed, the patients were moved to the post-anesthesia care unit (PACU) before being transferred to the ward. All subjects were instructed to rate their pain using a visual analog scale (VAS), where "0" indicated no pain and "10" represented the worst pain imaginable.

The time taken to perform TAP block was measured (from the time of needle insertion to the end of drug delivery), the comfort of the anaesthesiologist (5 point Likert scale), VAS score at 0,2,4,6,12,18 hours was assessed to assess the efficacy of the block performed, and time of the rescue analgesia given was noted.

STATISTICAL ANALYSIS

The observed data was analyzed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Chicago, IL). Descriptive statistics were presented as the mean (SD) for continuous variables and frequency (percentage) for categorical variables. The Chi-square test was employed to assess associations between categorical variables, while the independent t-test was used to examine associations between continuous variables in two groups.

OBSERVATION AND RESULTS

Table 1: Distribution of age among Group PH

Variable	**Group PH (n = 30)**
Age (in years)	27.9 ± 4.2

The table 1 shows the distribution of age among Group PH and the mean and SD of age among Group PH are 27.9 ± 4.2 years.

Table 2: Distribution of age among Group C

Variable	**Group C (n = 30)**
Age (in years)	26.4 ± 5.8

The mean & SD of age among Group C are 26.4 ± 5.8 years and it is represented in the bar chart.

Table 3: Comparing Age between two groups

Variable	**Group PH (n = 30)**	**Group C (n = 30)**	**p-value**
Age (in years)	27.9 ± 4.2	26.4 ± 5.8	0.2560

On comparing Group PH and Group C the mean & SD of age in the Group PH is greater than the Group C and it's not found to be significant.

Table 4: Time taken for a block among Group PH

Variable	**Group PH (n = 30)**
Time taken for block (in seconds)	217.10 ± 21.53

The table 4 depicts the Time taken for a block among Group PH and it is found to be 217.10 ± 21.53 (Mean & SD) seconds.

Table 5: Time taken for a block among Group C

Variable	Group C (n = 30)
Time taken for block (in seconds)	306.77 ± 18.25

The table 5 depicts the Time taken for a block among Group C and it is found to be 306.77 ± 18.25 (Mean & SD) seconds.

Table 6: Comparing Time taken for block among two groups

Variable	Group PH (n = 30)	Group C (n = 30)	P-value
Time taken for block	217.10 ± 21.53	306.77 ± 18.25	***0.0001****

p<0.05 considered as significant

On comparing Time taken for block among two groups. The patients in the Group PH 217.10 ± 21.53 seconds had quicker block than the Group C 306.77 ± 18.25 seconds.

Table 7: Comfort of the anaesthesiologist among Group PH

Variable	Group PH (n = 30)
Comfort	4.67 ± 0.47

The mean & SD of comfort among the Group PH are 4.67 ± 0.47

Table 8: Comfort of the anaesthesiologist among Group C

Variable	Group C (n = 30)
Comfort	2.63 ± 0.49

The mean & SD of comfort among the Group C are 2.63 ± 0.49

Table 9: Comparing Comfort among two groups

Variable	Group PH (n = 30)	Group C (n = 30)	P-value
Comfort	4.67 ± 0.47	2.63 ± 0.49	***0.0001****

p<0.05 considered as significant

On comparing the comfort among Group PH and Group C. The Group PH had better comfort than the Group C which is also found to be statistically significant (0.0001).

Table 10: VAS at 0 hour among two groups

VAS	Group PH (n = 30)	Group C (n = 30)
At 0 hour	0	0

At 0 hours the patients in the both the Groups PH and C experienced no pain as per Visual Analogue scale.

Table 11: VAS at 2 hours among Group PH

VAS	Group PH (n = 30)
At 2 hours	1.17 ± 0.37

Table 12: VAS at 2 hours among Group C

VAS	Group C (n = 30)
At 2 hours	1.20 ± 0.40

In the table 11 & 12 the VAS at 2 hours were demonstrated and among the two groups the patients in the Group C (1.20 ± 0.40) had more pain than the Group PH (1.17 ± 0.37). Their data were represented in the bar chart.

Table 13: VAS at 4 hours among Group PH

VAS	Group PH (n = 30)
At 4 hours	2.20 ± 0.40

Table 14: VAS at 4 hours among Group C

VAS	Group C (n = 30)
At 4 hours	2.27 ± 0.45

In the table 13 & 14 the VAS at 4 hours were demonstrated and among the two groups the patients in the Group C (2.27 ± 0.45) had more pain than the Group PH (2.27 ± 0.45). Their data were represented in the bar chart.

Table 15: VAS at 6 hours among Group PH

VAS	Group PH (n = 30)
At 6 hours	2.27 ± 0.45

Table 16: VAS at 6 hours among Group C

VAS	Group C (n = 30)
At 6 hours	2.23 ± 0.43

VAS at 6 hours the mean & SD among Group PH and Group C are 2.27 ± 0.45 and 2.23 ± 0.43 respectively. The Group C had experienced more pain than the Group PH.

Table 17: VAS at 12 hours among Group PH

VAS	Group PH (n = 30)
At 12 hours	2.17 ± 0.37

Table 18: VAS at 12 hours among Group C

VAS	Group C (n = 30)
At 12 hours	2.20 ± 0.40

Table 17 & 18 depicts the VAS at 12 hours among Group PH and Group C. The mean & SD of VAS at 12 hours are 2.17 ± 0.37 (Group PH) and 2.20 ± 0.40 (Group C).

Table 19: VAS at 18 hours among Group PH

VAS	Group PH (n = 30)
At 18 hours	2.20 ± 0.40

Table 20: VAS at 18 hours among Group C

VAS	Group C (n = 30)
At 18 hours	2.13 ± 0.34

VAS at 68 hours the mean & SD among Group PH and Group C are 2.20 ± 0.40 and 2.13 ± 0.34 respectively. The Group PH had experienced more pain than the Group C.

Table 21: VAS among two groups

VAS	Group PH (n = 30)	Group C (n = 30)	P-value
VAS 0hr	0	0	-
VAS 2hrs	1.17 ± 0.37	1.20 ± 0.40	0.7641
VAS 4hrs	2.20 ± 0.40	2.27 ± 0.45	0.5268
VAS 6hrs	2.27 ± 0.45	2.23 ± 0.43	0.7261
VAS 12hrs	2.17 ± 0.37	2.20 ± 0.40	0.7641
VAS 18hrs	2.20 ± 0.40	2.13 ± 0.34	0.4681

On comparing the VAS from 0 hours to 18 hours, both the group had similar pain intensity as per VAS. At 4 hours the Group C had more pain than the Group PH. At 18 hours the patients in the Group PH had more pain than the Group C. There was not much difference in pain intensity among two groups.

Table 22: Rescue analgesic request among two groups

Variable	Group PH (n = 30)	Group C (n = 30)
Rescue analgesic request (mins)	275.17 ± 22.57	274.63 ± 23.98

The Rescue analgesia among the Group PH and the Group C are 275.17 ± 22.57 seconds and 274.63 ± 23.98 mins. The rescue analgesic request was earlier among the Group C.

Table 23: Comparing Rescue analgesic request among two groups

Variable	Group PH (n = 30)	Group C (n = 30)	p-value
Rescue analgesic request	275.17 ± 22.57	274.63 ± 23.98	0.9287

The table 23 depicts the Comparing Rescue analgesic request among two groups and found the Group C had earlier request and as there was no marked difference among two groups and it is found to be insignificant.

DISCUSSION

Demographic characteristics

In our study, we found no statistically significant differences in demographic data (age, ASA grading, and surgical procedure) between the TAP block with probe holder and conventional method groups. This indicates that demographic factors were well matched and did not influence the outcomes. The mean age was 27.9 in group PH and 26.4 in group C and the difference was statistically insignificant.

Time taken to perform the block

In our study, the mean time to perform the TAP block with the newly developed 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is 217.10 seconds while the time taken to perform the TAP block with conventional USG method is 306.77 secs with a P value of 0.001 which is statistically significant.

A 2011 study by DJ Sandeman et al. investigated ultrasound-guided transversus abdominis plane (TAP) blocks for laparoscopic appendicectomy in children and concluded that TAP blocks extended anesthesia time by an average of 14 minutes (840 seconds). The more time required for the TAP block in this study might be due to the sample population (paediatric) on whom the study was conducted.

A 2020 study by Subbulakshmi et al. examined the accuracy and speed of ultrasound-guided transversus abdominis plane block using two different monitor positions. The mean values of the time taken to perform the TAP block were 69.08 +/- 8.19 and 80.6 +/- 4.84. The considerably lesser amount of time required for performing TAP block in this study was because only unilateral TAP blocks were performed in this study.

The results of our study directly imply that the time taken to perform the TAP block with 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is significantly more ergonomic than the conventional method.

Ease of anaesthesiologist to perform the block

In our study, the comfort of the anaesthesiologist to perform the TAP block was assessed using the 5-point Likert scale where 5 denotes extremely satisfied and 0 denotes extremely dissatisfied. The mean Likert score of the anaesthesiologist in performing the block using 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is 4.67 while the Likert score during conventional method is 2.63 with a P value of 0.001 which is statistically significant. This denotes the fact that the newly developed device provides more ease to the anaesthesiologist in performing the TAP block.

VAS scores

In our study, the VAS scores were assessed at 0, 2, 4, 6, 12, 18 hours after performing the TAP block. The mean of the VAS scores post TAP block using either the 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system or the conventional method were statistically insignificant. This directly denotes the TAP block performed with the 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is as precise as the conventional method.

A 2020 study by KP Manoj et al. compared the effectiveness of ultrasound-guided TAP block with multimodal analgesia. The mean of the VAS scores post TAP block at 0,4,8,12,24 hours were found to be 0.00±0.00, 0.87±1.28, 1.1±1.47, 0.93±1.31 and 0.3±0.75 respectively. The lower VAS scores in this study might be due to the addition of additive (Inj. Dexmeditomidine) to the local anaesthetic while performing the TAP block. In 2017,

Nabanita Das et al. conducted a study comparing the postoperative analgesic efficacy of TAP block and local site infiltration in cesarean sections. They recorded VAS scores at 0, 2, 6 and 24 hours of patients who received TAP blocks which were 0.00±0.00, 3.83 +/- 1.167, 3.9 +/- 0.6074, 3.966 +/- 0.6149, 2 +/- 0.3714, 1.967 +/- 0.4901 respectively. This results show that the pain scores recorded by Nabanita Das were comparable to the study conducted with the 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system.

Rescue analgesia

In our study, the time required for the first rescue analgesia request post the TAP block was noted. The mean of the time required for the first rescue analgesia request post the TAP block using either the 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system or the conventional method were statistically insignificant.

A 2020 study by D. Paul et al. compared the postoperative analgesic efficacy of TAP block with local anesthetic infiltration at the wound site. The time of the first rescue analgesia required was noted and was found to have a mean of 535.3 which is significantly higher than the rescue analgesia requirement in our study (275.17). This significant difference might be due to the additives in the local analgesia given to perform the block (Inj. Dexmeditomidine) which prolongs the duration of action of the TAP block.

A 2022 study by S. Khanna et al. compared the quadratus lumborum block to the transversus abdominis plane block for post-cesarean analgesia. The first rescue analgesia requirement in the study was found to be with a mean value of 5.99 hours which is statistically comparable to our study with 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system.

This directly implies the fact that the 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is as precise as the conventional method in providing TAP blocks.

CONCLUSION

The 3D printed hands-free reusable ultrasound probe holder with a multi angle needle guide system is more ergonomic in providing USG guided TAP block compared to the conventional method of USG guided TAP block. We also observed that the device is as efficacious as the conventional method in providing TAP block.

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